UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K/A
(Amendment No. 1)

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-40060

LONGEVERON INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-2174146**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
1951 NW 7th Avenue, Suite 520 Miami, Florida 33136	**33136**
(Address of Principal Executive Offices)	(Zip Code)

(305) 909-0840
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001	**LGVN**	**The Nasdaq Capital Market**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	
Non-accelerated filer ☒	Smaller reporting company ☒	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing

reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $19,016,000 as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter).

As of February 23, 2024, the registrant had 10,294,603 shares of Class A common stock, $0.001 par value per share, and 14,839,993 shares of Class B common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE. None

Auditor Name:	Auditor Location:	Auditor Firm ID:
Marcum LLP	Hartford, CT	688

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends the Annual Report on Form 10-K of Longeveron Inc. (the "Company") for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2024 (the "Original Form 10-K"). This Amendment is being filed solely to correct scrivener's errors in the Original Form 10-K under Part I, Item 1: Business in the description of the Company's owned intellectual property concerning (i) Mesenchymal stem cells as vaccine adjuvants and methods for using the same ("Patent Family 1") and (ii) methods of using human mesenchymal stem cells to effect cellular and humoral immunity ("Patent Family 2"). The Original Form 10-K erroneously disclosed that the Company (a) *owned and was continuing to prosecute and maintain* a U.S. patent application in Patent Family 1, (b) had one allowed patent application and one pending patent application in Japan in Patent Family 1 and (c) *received a notice of allowance* for certain patent applications in Patent Family 2. This Amendment corrects this disclosure to correctly indicate that the Company (x) *received a notice of allowance* for a U.S. patent application in Patent Family 1, (y) has two *pending* patent applications in Japan in Patent Family 1 and (z) *owns* certain patent applications in Patent Family 2.

As required under SEC rules, this Amendment sets forth the complete text of Part I, Item 1: Business, as amended and restated. In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), new certifications by the Company's principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment pursuant to Rules 13a-14(a) and 15(d)-14(a) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350).

Except as described above, no other changes have been made to the Original Form 10-K, and this Amendment does not otherwise amend, update or change the financial statements or other disclosures in the Original Form 10-K. This Amendment speaks as of the filing date of the Original Form 10-K and does not (i) reflect events, results or developments that occurred or facts that became known after the filing date of the Original Form 10-K or (ii) modify or update those disclosures affected by subsequent events, results, developments or facts. Among other things, forward-looking statements made in the Original Form 10-K have not been revised to reflect events, results or developments that occurred or facts that became known to us after the date of the Original Form 10-K, and such statements should be read in conjunction with our filings with the SEC subsequent to the Original Form 10-K. This Amendment should be read in conjunction with the Company's other filings with the SEC subsequent to February 27, 2024.

PART I

Item 1. Business

Overview

We are a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The Company's lead investigational product is Lomecel-B™, an allogeneic Mesenchymal Stem Cell ("MSC") formulation sourced from the bone marrow of young, healthy adult donors. Lomecel-B™ has multiple potential mechanisms of action that promote tissue repair and healing with broad potential applications across a spectrum of disease areas. The underlying mechanism(s) of action that may lead to the tissue repair programs include the stimulation of new blood vessel formation, modulation of the immune system, reduction in tissue fibrosis, and the stimulation of endogenous cells to divide and increase the numbers of certain specialized cells in the body.

We are currently pursuing three pipeline indications: Hypoplastic Left Heart Syndrome ("HLHS"), Alzheimer's disease ("AD") and Aging-related Frailty. Our mission is to advance Lomecel-B™ and other cell-based product candidates into pivotal or Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

In November of 2023, Longeveron received notice from the World Health Organization ("WHO") that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

HLHS

Our HLHS program is focused on the potential clinical benefits of Lomecel-B™ as an adjunct therapeutic to standard-of-care HLHS surgery. HLHS is a rare and devastating congenital heart defect in which the left ventricle is severely underdeveloped. As such, babies born with this condition die shortly after birth without undergoing a complex series of reconstructive heart surgeries. Despite the availability of life-saving surgical interventions, clinical studies show that only 50 to 60 percent of affected individuals survive to adolescence. Early clinical study data shows the potential survival benefit of Lomecel-B™ for HLHS patients and supports Longeveron's belief that this data shows the potential to alter the treatment landscape for patients with HLHS. We have completed a Phase 1 open-label study ("ELPIS I")[1] that supported the safety and tolerability of Lomecel-B™ for HLHS, when directly injected into the functional right ventricle during the second-stage standard-of-care surgery (adding minimal additional time to the surgical procedure). Preliminary data revealed that several indices of right ventricular function show suggestions of either improvement or prevention of deterioration over one year following surgery. Heart transplant-free survival for patients who received Lomecel-B™ intracardiac injection is favorable as compared to historical controls for survival. The improvement in HLHS survival following the Phase 1 ELPIS I clinical trial has resulted in acceptance by the American Heart Association ("AHA") for a poster presentation at an AHA meeting in November 2023. The ELPIS I trial showed 100 percent survival in children up to 5 years of age after receiving Lomecel-B™, compared to a 20 percent mortality rate observed from historical control data. Based on these findings, the U.S. Food and Drug Administration (the "FDA") granted Lomecel-B™ both Rare Pediatric Disease (RPD") Designation and Orphan Drug Designation ("ODD") for treatment of infants with HLHS. Longeveron is currently conducting a controlled Phase 2b trial ("ELPIS II") to compare the effects of Lomecel-B™ as an adjunct therapeutic versus standard-of-care (HLHS surgery alone). We hope that a positive outcome could add to the clinical data suggesting the functional and clinical benefit of Lomecel-B™ as part of standard-of-care treatment in HLHS patients.

[1] Sunjay Kaushal, MD, PhD, Joshua M Hare, MD, Jessica R Hoffman, PhD, Riley M Boyd, BA, Kevin N Ramdas, MD, MPH, Nicholas Pietris, MD, Shelby Kutty, MD, PhD, MS, James S Tweddell, MD, S Adil Husain, MD, Shaji C Menon, MBBS, MD, MS, Linda M Lambert, MSN-cFNP, David A Danford, MD, Seth J Kligerman, MD, Narutoshi Hibino, MD, PhD, Laxminarayana Korutla, PhD, Prashanth Vallabhajosyula, MD, MS, Michael J Campbell, MD, Aisha Khan, PhD, Eric Naioti, MSPH, Keyvan Yousefi, PharmD, PhD, Danial Mehranfard, PharmD, MBA, Lisa McClain-Moss, Anthony A Oliva, PhD, Michael E Davis, PhD, Intramyocardial cell-based therapy with Lomecel-B™ during bidirectional cavopulmonary anastomosis for hypoplastic left heart syndrome: The ELPIS phase I trial, *European Heart Journal Open*, 2023.

Alzheimer's Disease

In September 2023, we completed our Phase 2a AD clinical trial, known as the CLEAR MIND trial. This trial enrolled patients with mild Alzheimer's disease and was designed as a randomized, double-blind, placebo-controlled study across ten U.S. centers. Our primary objective was to assess safety, and we tested three distinct Lomecel-B™ dosing regimens against placebo.

The study demonstrated positive results. Notably, all Lomecel-B™ treatment groups met the safety primary endpoint and showed slowing/prevention of disease worsening relative to placebo. There were statistically significant improvements in the secondary efficacy endpoint, composite Alzheimer's disease score ("CADS") for both the low-dose Lomecel-B™ group and the pooled treatment groups compared to placebo. Other doses also showed promising results in slowing/prevention of disease worsening. Additionally, a statistically significant improvement versus placebo was observed in the cognitive assessment ("MoCA") and in the activity of daily living observed by a caregiver and measured by Alzheimer's Disease Cooperative Study Activities of Daily Living ("ADCS-ADL"). These findings support both the safety and potential therapeutic benefit of Lomecel-B™ in managing mild Alzheimer's disease, and we believe lays a strong groundwork for subsequent trials in this indication.

Aging-related Frailty

Improvement of the quality of life for the aging population is one of the strategic directions of the Company. Life expectancy has substantially increased over the past century due to medical and public health advancements. However, this longevity increase has not been paralleled by health span – the period of time one can expect to live in relatively good health and independence. For many developed and developing countries, health span lags life-expectancy by over a decade. This has placed tremendous strain on healthcare systems in the management of aging-related ailments and presents additional socioeconomic consequences due to patient decreased independence and quality-of-life. Since these strains continue to increase with demographic shifts towards an increasingly older population, improving health span has become a priority for health agencies, such as the National Institute on Aging ("NIA") of the National Institutes of Health ("NIH"), the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), and the European Medicines Agency ("EMA"). As we age, we experience a decline in our own stem cells, a decrease in immune system function (known as "immunosenescence"), diminished blood vessel functioning, chronic inflammation (known as "inflammaging"), and other aging-related alterations that affect biological functioning. Our preliminary clinical data suggest that Lomecel-B™ may potentially address these problems through multiple potential mechanisms of action ("MOAs") that simultaneously target key aging-related processes. We are using Lomecel-B™ in registry trials in The Bahamas as part of the real-world data generation for the aging population.

Summary of Clinical Development Strategy

Our core strategy is to become a world-leading regenerative medicine company through the development, approval, and commercialization of novel cell therapy products for unmet medical needs, with a focus on HLHS. Key elements of our current business strategy are as follows.

- Execution of ELPIS II, a Phase 2b randomized controlled trial set forth in greater detail below, to measure the efficacy of Lomecel-B™ in HLHS. This trial is ongoing and is being conducted in collaboration with the National Heart, Lung, and Blood Institute ("NHLBI") through grants from the NIH.

- Continue to pursue the therapeutic potential of Lomecel-B™ in mild AD. We completed a Phase 2a trial, the ("CLEAR MIND Trial"), which demonstrated the potential benefits of Lomecel-B™ over placebo to maintain cognitive function and slow deterioration of brain structure atrophy, with no safety issues observed. Specifically, the safety primary endpoint was met across all study groups and the trial demonstrated a statistical significance in the second CADS endpoint. Overall, in Lomecel-B™ groups, brain magnetic resonance imaging ("MRI") demonstrated whole brain volume loss slowed accompanied by significant preservation of left hippocampal volume relative to placebo. We plan to continue to analyze the data in order to further develop our clinical development strategy. Our objective is to forge strategic collaborations for the advancement of Lomecel-B™ in addressing AD. We are actively in pursuit of a partnership to propel this initiative forward.

- Limited focus on our international program. In line with the Company's strategic direction for 2024 and moving forward to focus on HLHS and AD as set forth previously, the Company has discontinued its clinical trial in Japan to evaluate Lomecel-B™ for Aging-related Frailty.

  The Company will continue to enroll patients on the Frailty and Cognitive Impairment registry trials in The Bahamas and plans to also launch an Osteoarthritis registry trial.

- Expand our manufacturing capabilities to commercial-scale production. We operate a current good manufacturing practice ("cGMP")-compliant manufacturing facility and produce our own product candidates for testing. We continue to improve and expand our capabilities with the goal of achieving cost-effective manufacturing that may potentially satisfy future commercial demand for potential Lomecel-B™ commercialization.

- Collaborative arrangements and out-licensing opportunities. We will be opportunistic and consider entering into co-development, out-licensing, or other collaboration agreements for the purpose of eventually commercializing Lomecel-B™ and other products domestically and internationally if appropriate approvals are obtained.

- Product candidate development pipeline through internal research and development, and in-licensing. Through our research and development program, and through strategic in-licensing agreements, or other business development arrangements, we intend to actively explore promising potential additions to our pipeline.

- Continue to expand our intellectual property portfolio. Our intellectual property is vitally important to our business strategy, and we have taken and continue to take significant steps to develop this property and protect its value. Results from our ongoing research and development efforts are intended to add to our existing intellectual property portfolio.

Clinical Development Pipeline in 2024

We are currently in clinical development of a single product, Lomecel-B™ for three potential indications:

Indication	Geography	Phase 1	Phase 2	Phase 3
HLHS	U.S.			
Aging-related Frailty*	U.S.			
Alzheimer's disease	U.S.			

Figure 1: Lomecel-B™ clinical development pipeline

* Not currently active for 2024

Hypoplastic Left Heart Syndrome (HLHS). The FDA granted Lomecel-B™ for the treatment of HLHS a Rare Pediatric Disease ("RPD") Designation (on November 8, 2021), Orphan Drug Designation ("ODD") (on December 2, 2021), and Fast Track Designation (on August 24, 2022). HLHS is a rare congenital heart condition affecting approximately 1,000 newborns in the US annually. HLHS is a birth defect that affects normal blood flow through the heart. As the baby develops during pregnancy, the left side of the heart does not form correctly. It is one type of congenital heart defect present at birth. Because a baby with this defect needs surgery or other procedures soon after birth, HLHS is considered a critical congenital heart defect. To prevent certain death shortly after birth, these babies undergo a series of three heart surgeries (staged surgical palliation) that converts the normally 4-chamber heart into a 3-chamber one with a single ventricle (the right ventricle) supporting systemic circulation. Despite these life-saving surgeries, HLHS patients nevertheless still have high early mortality and morbidity rates due primarily to heart failure.

We are currently conducting an ongoing Phase 2 clinical trial (ELPIS II) under FDA IND 017677. ELPIS II is a multi-center, randomized, double-blind, controlled clinical trial designed to evaluate Lomecel-B™ as an adjunct therapy to the standard-of-care second-stage HLHS heart reconstructive surgery which is typically performed at 4-6 months after birth. The primary objective is to evaluate change in right ventricular ejection fraction after Lomecel-B™ treatment versus standard-of-care surgery alone (38 subjects total: 19 per arm). This trial is over 50% enrolled and is funded in part by the NHLBI/NIH. While we cannot predict a specific time when the trial will be fully enrolled, the current plan is that enrollment will be completed in 2024.

ELPIS II is a next-step trial to our completed 10-patient open-label Phase 1 trial (ELPIS I) under the same IND. This Phase 1 trial was designed to evaluate the safety and tolerability of Lomecel-B™ as an adjunct to the second-stage HLHS surgery, and to obtain preliminary evidence of Lomecel-B™ effect to support a next-phase trial. The primary safety endpoint was met: no major adverse cardiac events ("MACE") or treatment-related infections during the first month post-treatment, and no triggering of stopping rules. Furthermore, fluid-based and imaging biomarker data supported multiple potentially relevant mechanisms-of-action of Lomecel-B™, and the potential to improve post-surgical heart function. In addition to the 12-month follow-up evaluation on ELPIS, we continue to follow these patients on an annual basis. As of February 2024, all 10 patients have survived (100%), seven of the patients have reached the age of five and have successfully undergone the third-stage surgery, and two of them have reached the age of six years old, all without the need for a heart transplantation. Based on historical data, over 15% of patients would be expected to have received a heart transplant or have died within three years after the second-stage surgery, rising to nearly 20% by five years. We intended to continue to follow-up with these patients for up to an additional five years, until all patients reach ten years of age.

We are prosecuting a number of patent applications relating to the administration of mesenchymal stem cells for treating HLHS in Canada, Japan, Taiwan, the United States and the Bahamas, with applications having also been ordered for filing in Australia, China, South Korea, and the European Patent Office.

Alzheimer's disease. AD, a devastating neurologic disease leading to cognitive decline, currently has very limited therapeutic options. An estimated 6.7 million Americans aged 65 and older have AD, and this number is projected to more than double by 2060. Lomecel-B™ treated patients showed an overall slowing/prevention of disease worsening compared to placebo in the completed Phase 2a study (CLEAR MIND) as previously detailed in this report, and met its primary endpoint of safety. These results are consistent with those of our earlier Phase I study[2]. As previously indicated, we are actively in pursuit of a partnership to propel our AD initiative forward.

Aging-related Frailty. Aging-related Frailty is a life-threatening geriatric condition that disproportionately increases risks for poor clinical outcomes from disease and injury. While the definition of Aging-related Frailty lacks consensus, would be a new indication from a regulatory standpoint, and has no approved pharmaceutical or biologic treatments, there are a number of companies now working to develop potential therapeutics for this unmet medical need.

We have previously completed two U.S. clinical trials under FDA IND 016644. One is a multicenter, randomized, placebo-controlled Phase 2b trial which showed that a single infusion of Lomecel-B™ significantly improved 6-Minute Walk Test ("6MWT") distance 9 months after infusion (although results were inconclusive at six months after infusion), and also showed a dose-dependent increase in 6MWT distance 6 months after infusion. The second is a multicenter, randomized, placebo-controlled Phase 1/2 trial ("HERA Trial") intended primarily to evaluate safety, and explore the effect Lomecel-B™ may have on specific biomarkers of immune system function in older, frail individuals receiving the high dose influenza vaccine, as well as to evaluate the potential effects of Lomecel-B™ on signs and symptoms of Aging Frailty. Results from this study showed that Lomecel-B™ was generally safe and well tolerated in patients with Aging-related Frailty. Additionally, hemagglutinin inhibition ("HAI") assay results in the Lomecel-B™ and placebo groups to influenza were not statistically different, indicating Lomecel-B™ does not suppress the immune system.

2 Mark Brody, Marc Agronin, Brad J. Herskowitz, Susan Y. Bookheimer, Gary W. Small, Benjamin Hitchinson, Kevin Ramdas, Tyler Wishard, Katalina Fernández McInerney, Bruno Vellas, Felipe Sierra, Zhijie Jiang, Lisa McClain-Moss, Carmen Perez, Ana Fuquay, Savannah Rodriguez, Joshua M. Hare, Anthony A. Oliva Jr., Bernard Baumel. "Results and insights from a phase I clinical trial of Lomecel-B™ for Alzheimer's disease" (2023) Alzheimer's & Dementia: The Journal of the *Alzheimer's Association 19:261-273.*

We are prosecuting or have sent filing instructions for a number of patent applications relating to the administration of MSC for Aging-related Frailty in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Singapore, South Korea, New Zealand, Taiwan, the Bahamas and United States.

Manufacturing

The manufacture and delivery of cell therapy products to patients involves complex, integrated processes. Commercial success in this area requires manufacturing processes that are reliable, scalable, and economical. We currently operate a manufacturing facility in Miami, Florida, which supplies Lomecel-B™ for our clinical trials and also serves as our corporate headquarters. We have devoted and plan to continue devoting significant resources to optimization of process development and manufacturing to reduce per-unit manufacturing costs and to enable quick scale-up of production upon approval of any of our candidates in a particular country.

Our current good manufacturing process ("cGMP") facility went online in early 2017 and consists of 4,150 ft^2 (385.5 m^2) with approximately 3,000 ft^2 (279 m^2) of cGMP space comprised of eight International Organization for Standardization ("ISO") 7 cleanrooms, and ISO 8 ancillary areas and 1,150 ft^2 (107 m^2) of warehouse, research and development and Quality Control space, including two research and development laboratories. The cGMP cleanrooms are used exclusively for the manufacture of human cellular therapy products for use in clinical trials. The facility is in compliance with FDA regulations in the Code of Federal Regulations 21, Parts 210 and 211.

Our lead product, Lomecel-B™, consists of human allogeneic bone-marrow derived MSCs as the active ingredient. These cells undergo culture-expansion using proprietary processes, and are then formulated, packaged and stored frozen (cryopreserved) until shortly before use**.** Fresh bone marrow is procured from established, licensed U.S.-based third-party tissue suppliers, which harvest the tissue from young, healthy consenting adult donors. Lomecel-B™ is produced using processes that FDA has reviewed and authorized as part of our INDs. We currently have bone marrow supply contracts in place with two suppliers: the Oklahoma Blood Institute and All Cells, with a potential third vendor in process. These suppliers provide adequate bone marrow for our current and anticipated needs; however, if one or both suppliers were to no longer provide bone marrow, alternate suppliers would be needed or our ability to produce Lomecel-B™ in the future could be impacted.

Technology Capabilities

From the commencement of operations in 2014, we recognized the potential for a cellular therapy product to be a novel therapeutic candidate in our chosen indications. We have assembled a team of experts and proprietary technologies that we believe enables us to take a systematic approach to rapidly develop improved cell therapies. We believe having established manufacturing capabilities and operations within the U.S. early in the development of our product candidates is a competitive advantage. Over time, as needed and appropriate, we expect to expand regional manufacturing capacity and potentially add external supply nodes to meet projected product requirements for commercialization. We believe that anticipated future clinical and commercial demand for Lomecel-B™ and new pipeline programs can be met, as our process has been designed to meet these demands as milestones are achieved. We believe our scalable robust manufacturing process, along with our proprietary technologies and our industry experienced team, would be challenging and costly for potential competitors to replicate.

Contract Development and Manufacturing Services

We produce all of our product candidates in the ISO 7 cleanrooms of our cGMP facility to satisfy our ongoing clinical studies and The Bahamas Registry Trial. As a revenue-generating opportunity, occasionally we utilize excess capacity, when available, to provide contract manufacturing and development services to third parties; however, our business development activity is limited in this area.

Commercialization

We currently have no established sales, marketing or product distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we will need a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third parties that have sales and marketing experience. As we move our product candidates through development toward regulatory approval, we plan to evaluate several options for each product candidate's commercialization strategy. These options include further building an internal sales force, entering into a joint marketing collaboration with another pharmaceutical or biotechnology company, or out-licensing any future approved product to another pharmaceutical or biotechnology company. All such commercialization will be undertaken in accordance with applicable law.

Competition

The field of regenerative medicine, which includes gene therapies, cell therapies (such as Lomecel-B™), and tissue-engineered products, is broadly defined as "products intended to repair, replace or regenerate organs, tissues, cells, genes, and metabolic processes in the body," per the Alliance for Regenerative Medicine ("ARM"), an international advocacy organization. Regenerative medicine companies number over 1,550 worldwide as of January 2024.

In some of our indications, we face competition from both cellular therapy companies, and pharmaceutical/biotechnology companies. In the following table is a general, non-comprehensive list of cellular therapy companies that we believe could be considered our primary competition, either because they also develop MSCs as their primary mode of action, albeit for different indications in most cases or on the basis that these companies are addressing the same indications as Longeveron.

Name	Corporate Headquarters	Clinical stage pipeline indication(s)
Athersys, Inc.	U.S.	Ischemic stroke; ARDS; GvHD; Acute Myocardial Infarction
BioCardia, Inc.	U.S.	Heart failure; Acute myocardial infarction
BrainStorm Cell Therapeutics	U.S.	ALS; MS
Lisata Therapeutics	U.S.	Coronary microvascular dysfunction; Critical limb ischemia; Diabetic kidney disease
CorestemChemon	South Korea	ALS (Commercial in South Korea); Lupus
Cynata Therapeutics	Australia	GvHD
Healios K.K.	Japan	Ischemic stroke; ARDS
Medipost	South Korea	Osteoarthritis (commercial); BPD; AD
Mesoblast Ltd.	Australia	Heart failure, low back pain, GvHD; ARDS; Crohn's Disease, HLHS
Pluri, Inc.	Israel	CLI; ARDS; ARS; GvHD
ReNeuron	U.K.	Ischemic stroke; Retinitis pigmentosa
SanBio Co., Ltd.	Japan	Ischemic stroke; Traumatic brain injury
Stemedica Cell Technologies	U.S.	Ischemic stroke; heart failure; AD

ARDS = Acute Respiratory Distress Syndrome; GvHD = Graft versus host disease; ALS = Amyotrophic lateral sclerosis; MS = Multiple sclerosis; BPD = Bronchopulmonary dysplasia; CLI = Critical limb ischemia; CMD = Coronary microvascular disease; ARS = Acute radiation syndrome.

Aging Frailty Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 107 clinical trials in Aging Frailty listed on the site including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Of the 107 listed studies, there were 29 studies listed which are currently enrolling patients with aging frailty. Among those, allogeneic bone-marrow-derived mesenchymal stem cell were listed as an intervention in three studies:

- "A Study to Evaluate Allogenic Bone-Marrow Mesenchymal Stromal Cell Product StromaForte in Aging Frailty Patients", sponsored by Cellcolabs Clinical SPV Limited. This phase I/IIa study in frail patients is designed to assess the safety of intravenous human allogenic bone marrow-derived mesenchymal stromal cell product StromaForte by reporting the number of adverse events assessed by Common Terminology Criteria. 12 male and female patients aged 60 to 85 years will be enrolled. The study initiated on October 2, 2023, with estimated completion date November 28, 2024. The study is currently enrolling patients in United Arab Emirates.

- "Safety of Cultured Allogeneic Adult Umbilical Cord Derived Mesenchymal Stem Cell Intravenous Infusion for Aging Frailty", sponsored by The Foundation for Orthopedics and Regenerative Medicine. This trial will study the safety and efficacy of intravenous infusion of cultured allogeneic adult umbilical cord derived mesenchymal stem cells for the treatment of Aging Frailty. The plan is to enroll 20 patients. The study initiated on August 24, 2021 and estimated completion study date is December 1, 2027.

- "A Study of Human Allogeneic Bone-marrow-derived Mesenchymal Stromal Cell Product (StromaForte) in Patients With Aging Frailty", sponsored by Cellcolabs Clinical LTD. The goal of this phase I/II clinical trial is to evaluate the safety and tolerability of intravenous infusion of human allogeneic bone-marrow-derived mesenchymal stromal cell product StromaForte in patients with aging frailty. The main questions it aims to answer are: 1) To assess the safety and tolerability after 28 days of injection by reporting the number of adverse events assessed by Common Terminology Criteria For Adverse Events ("CTCAE") 2) Observe the change in inflammatory markers from baseline to six months (baseline to 28, 84, and 168 days post-infusion.). The study was initiated on October 9, 2023 and the estimated date of completion is January 10, 2025.

Alzheimer's Disease Competitive Intelligence Research

Per ClinicalTrials.gov, as of February 18, 2024, there were 3,334 studies listed on the site studying Alzheimer's disease, including all stages (ongoing, completed, terminated, withdrawn) and all interventions. Among those, 401 studies were listed with Alzheimer's disease as an indication and stem cells as an intervention. Seventeen of them were listed to conduct clinical studies with mesenchymal stem cells in all stages and only one of them is currently enrolling patients on the study:

- "Allogeneic Human Mesenchymal Stem Cells for Alzheimer's Disease", Phase 2 study, sponsored by Stemedica Cell Technologies, Inc. The main goals of this study are 1) To assess the safety and tolerability of ischemia-tolerant allogeneic human mesenchymal stem cells ("hMSCs") manufactured by Stemedica versus placebo administered intravenously to subjects with mild to moderate dementia due to Alzheimer's disease and 2) To assess the preliminary efficacy of hMSCs versus placebo in subjects with Alzheimer's-related dementia, as evidenced by neurologic, functional, and psychiatric endpoints. This study planned to enroll 40 patients in United States, California. The study was initiated on June 1, 2016, and the estimated study completion date is December 31, 2024.

There are many other pharmaceutical and biotechnology companies that are conducting clinical trials of various therapeutics for the treatment of AD.

Intellectual Property

We seek to protect our proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired from third parties, or licensed from third parties. We also intend to seek and rely on any statutory or regulatory protections, including FDA's expedited review program, data exclusivity, market exclusivity and patent term extensions where available.

By letter dated November 20, 2023, Longeveron was informed by the WHO that "laromestrocel" has been selected as the proposed International Nonproprietary Name for Longeveron's Lomecel-B™ product. Assuming that there are no third-party objections to that name, the name will be recommended for adoption by the WHO. Longeveron will adopt that name if it is recommended by the WHO.

We have a combination of Company-owned and in-licensed patents and patent applications related to cell-based therapy and its various uses. This portfolio includes patent applications directed to use of allogeneic MSCs to treat sexual dysfunction. We also have in-licensed a patent family directed to methods of use of CD271+ MSC precursor cells. Our patent applications contain claims that, if allowed, specifically protect the use of our product in individuals with Aging-related frailty, immunosenescence, and other age-related diseases. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and enforce and therefore provide us with only limited protection.

We expect to file additional patent applications in support of current and new product candidates, as well as for process and manufacturing-related improvements or inventions, should these arise. These expected additional patent applications may be related to existing patent applications or may create new patent families. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our current and future product candidates and the methods used to develop, manufacture, administer, and use them. Our commercial success will also depend on successfully defending our patents against third-party challenges and operating without infringing on the proprietary rights of others. We are aware of several U.S. patents held by third parties covering potentially similar or related products, and their manufacture and use. Generally, conducting clinical trials and other acts relating to FDA approval are not considered acts of infringement in the U.S. If and when Lomecel-B™ MSCs are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Our ability to deter and, if necessary, to stop third parties from making, using, selling, offering to sell or importing our products or products that are similar to our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We can neither be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. Unpublished third-party patent applications may exist that would have an effect on our freedom to operate. For this and more comprehensive risks related to our intellectual property, please see "*Risk Factors—Risks Related to Intellectual Property*."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most jurisdictions where we file, including the U.S., the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the U.S., a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office "(USPTO"), in examining and granting a patent. Patent term in the U.S. may be shortened if a patent is subject to a terminal disclaimer over another patent. Delays on the part of a patentee may decrease patent term adjustment.

In the U.S., the term of a patent that covers an FDA-approved "active ingredient" or methods of its use may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Amendments, or the Biologics Price Competition and Innovation Act of 2009 permit a patent term extension of up to five years beyond the expiration of the statutory term of a patent, including any patent term adjustment to which the patent is entitled. The length of the patent term extension is related to the length of time the active ingredient or method is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions for any issued patents we may obtain in any jurisdiction where such patent term extensions are available. We are not assured that the applicable authorities, including the FDA in the U.S., will agree with our assessment of whether such extensions should be granted, and if granted, the length of those extensions. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to Intellectual Property*."

We may file patent applications directly with the USPTO as provisional applications. We may file U.S. non-provisional applications, direct foreign applications under the Paris Convention and the Agreement on Trade Related Aspects of Intellectual Property Rights, and Patent Cooperation Treaty, or PCT, applications. Those applications may claim the benefit of the priority date of one or more earlier filed applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application and to designate all of the PCT member states in which national or regional patent applications can later be pursued based on the PCT application.

For all patent applications, we determine claim strategy on a case-by-case basis. Advice of counsel and our business model and needs are considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We routinely reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes and compositions. Further, we may modify claims during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors. These include the volume and scope of the prior art, the novelty, non-obviousness, and utility of the invention, and the ability to satisfy the written description and enablement requirements of the patent laws. In addition, the coverage claimed in a patent application can be significantly narrowed before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will be issued as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from copying by competitors. Any patents that we hold may be challenged, circumvented, or invalidated by third parties. We cannot predict whether, in certain jurisdictions, a third-party will use a method confidentially that we later independently discover and patent, which may result in a limited grant to the third party of the ability to continue to practice that method despite our patent.

In addition to patent protection, we rely on trademark registration, trade secrets, know-how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contracts with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets indefinitely.

We require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except under specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors, or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see "*Risk Factors—Risks Related to Intellectual Property*."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific, and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies or our products or processes, to obtain licenses or to cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. If third parties file requests for *inter partes* review of our patents, then we may have to defend those patents in the USPTO. For more information, see "*Risk Factors—Risks Related to Intellectual Property*."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

Company-Owned Intellectual Property

Mesenchymal Stem Cells as Vaccine Adjuvants and Methods for Using the Same. The claims within this patent application family are currently directed to methods of enhancing the immune response to vaccination, which was one of the research objectives of our Phase 1/2 HERA Trial. This research is relevant to Aging-related Frailty subjects, who are particularly vulnerable to the effects of viral contagion, such as influenza or COVID-19, and who may be lacking in immunoprotection. Certain claims address the ability to enhance a subject's immune response to a vaccine through the administration of a therapeutically effective amount of allogeneic MSCs in a subject that exhibits "inflammaging." In this family we received a notice of allowance for our U.S. patent application, and we have two pending applications in Japan, one pending application in Australia, and one pending application in the European Patent Office. Another European Patent Office application has been allowed, and pending conclusion of the opposition period is planned to be validated in Switzerland, Germany, Spain, France, Great Britain, Italy, and Sweden. All of the patent applications are national or regional phase applications based on a Patent Cooperation Treaty ("PCT") application filed in February 2017 and claiming priority to a U.S. provisional application filed in February 2016. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in 2037. Longeveron has elected to take no further action and to allow to become abandoned, properties in this family in Canada, Hong Kong, Israel, Singapore, South Africa, South Korea, and New Zealand.

*Methods of Using Human Mesenchymal Stem Cells to Effect Cellular and Humoral Immunity***.** Certain claims in this family of patent applications relate to the ability for MSC therapy to improve the immune system function in patients with chronic systemic inflammation, a hallmark of frailty. It is believed that raising or lowering specific biomarkers after therapeutic intervention by a minimum amount may provide broad protection from an intellectual property standpoint and reflects clinical goals of treatment and treatment response.

In this family we own one pending U.S. patent application, and 14 patent applications outside of the U.S. (in 12 jurisdictions). The Chinese counterpart of the application has been allowed. Patents have issued in Japan and Taiwan, and a patent registration has issued in South Africa. With two exceptions (The Bahamas and Taiwan), all of the applications are national or regional phase applications based on a PCT application filed in November 2017 and claiming priority to a U.S. provisional application filed in November 2016. The applications in The Bahamas and Taiwan claim priority to that same provisional application but were not filed using the PCT. In addition to the applications in Taiwan and The Bahamas, PCT national or regional phase applications were filed in the U.S., Australia, Canada, China, the European Patent Organization, Israel, Japan, South Korea, New Zealand, Singapore, South Africa, and Hong Kong. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in 2037.

*Treatment of Sexual Dysfunction and Improvement in Sexual Quality of Life***.** This application family is directed towards increasing libido and improving sexual function and satisfaction in a female patient through the use of allogeneic or autologous MSC therapy, whether derived from bone marrow, adipose tissue or induced pluripotent stem cells (iPSCs). In this family we own and we are continuing to prosecute or maintain applications in the United States and European Patent Office, and we own a patent in Japan. We also won and are continuing to maintain a patent registration in the Bahamas. The U.S., Japanese, and European properties are a national or regional phase applications based on a PCT application filed on June 15, 2018 and claiming priority to a U.S. provisional application filed in June 2017. The registration in the Bahamas claims priority to that same provisional application but was not filed using the PCT. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in June 2038. Longeveron has elected to take no further action and to allow to become abandoned, properties in the family in Australia, Canada, China, Hong Kong, Israel, Korea, Singapore, South Africa, South Korea, Taiwan, and New Zealand.

Potency Assay. This application family is directed towards assessing potency of MSCs to produce anti-inflammatory cytokines in response to a pro-inflammatory stimulus. In this family we own pending applications in Australia, the Bahamas, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, New Zealand, the Republic of Korea, Singapore, South Africa, and the United States. These applications have a filing date in April 2021 and claim priority to a U.S. provisional application filed in April 2020. If issued and assuming that all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in April 2041.

Use of Mesenchymal Stem Cells in Treatment of Juvenile Hypoplastic Left Heart Syndrome. This patent family is directed to treatment of HLHS with allogeneic MSCs. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. These applications share a common priority date of July 2021. National and regional phase applications based on pending PCT application, have been filed or are expected to be filed in Australia, Canada, China, the European Patent Office, Japan, South Korea, Taiwan, and the United States. If issued and assuming all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in July 2042.

Administration of Mesenchymal Stem Cells for Aging-related frailty. This patent family relates to administration of MSCs for Aging-related frailty. In this family we own pending applications in Taiwan, the Bahamas, and the PCT. These applications share a common priority date of September 2021. National and regional phase applications, based on the pending PCT application have been filed or are expected to be filed in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, New Zealand, South Korea, Singapore, and South Africa. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are projected to expire in September 2042.

Treatment of Alzheimer's Disease with Allogeneic Mesenchymal Stem Cells. This patent family relates to administration of MSCs to treat AD. We own pending patent applications in Australia, the Bahamas, South Korea, Singapore, South Africa, Israel, Canada, Hong Kong, New Zealand, China, Japan, the European Patent Office, and the United States. Those applications claim priority to three separate U.S. provisional applications, the earliest of which was filed in September 2020. If issued, and assuming that all maintenance and annuity fees are paid, patents arising from these applications are expected to expire in September 2041.

License Agreements and Strategic Collaborations

The University of Miami ("UM")

On November 20, 2014, we entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related frailty-related MSC technology rights developed by our Chief Science Officer, Dr. Joshua Hare, at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for aging-related frailty used at the Interdisciplinary Stem Cell Institute of UM ("IMSCs"), all standard operating procedures used to create the IMSCs, and all data supporting isolation, culture, expansion, processing, cryopreservation, and management of the IMSCs. We are required to pay UM (i) a license issue fee of $5,000, (ii) a running royalty in an amount equal to three percent of annual net sales on products or services developed from the technology, payable on a country-by-country basis beginning on the date of first commercial sale through termination of the UM License Agreement, and which may be reduced to the extent we are required to pay royalties to a third party for the same product or process, (iii) escalating annual cash payments of up to fifty thousand dollars, subject to offset. The agreement extends for up to 20 years from the last date a product or process is commercialized from the technology and was amended in 2017 to modify certain milestone completion dates as detailed below. In 2021 the license fee was increased by an additional $100,000, to defray patent costs. In addition, the Company issued 110,387 unregistered shares of Class A common stock to UM.

The milestone payment amendments shifted the triggering payments to three payments of $500,000, to be paid within six months of: (a) the completion of the first Phase 3 clinical trial of the products (based upon the final data unblinding); (b) the receipt by the Company of approval for the first new drug application ("NDA"), biologics application ("BLA"), or other marketing or licensing application for the product; and (c) the first sale following product approval. "Approval" refers to product approval, licensure, or other marketing authorization by the U.S. Food and Drug Administration, or any successor agency. The amendments also provided for the Company's license of additional technology, to the extent not previously included in the UM License and granted the Company an exclusive option to obtain an exclusive license for (a) the HLHS IND with ckit+ cells; and (b) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

We have the right to terminate the UM License upon 60 days' prior written notice, and either party has the right to terminate upon a breach of the UM License. To date, the Company has made payments totaling $365,000 to UM, and as of December 31, 2023, we had accrued $50,000 in milestone fees payable to UM.

CD271

On December 22, 2016, we entered into a worldwide exclusive license agreement with JMH MD Holdings ("JMHMD"), an affiliate of our Chief Science Officer, Dr. Joshua Hare, for the use of CD271 cellular therapy technology. We are required to pay JMHMD a running royalty in an amount equal to one percent of the annual net sales of the licensed product(s) used, leased, or sold by or for us by any sub-licensees, which amounts are payable on a country-by-country basis beginning on the date of first commercial sale and ending on the latter of expiration of the last to expire patent rights in such country or ten years from the first commercial sale in such country (provided that if all claims within the patent rights have expired or been finally deemed invalid then the royalty will be reduced by 50%), and which may also be reduced to the extent we are required to pay royalties to a third party for the same product or process. We are also required to pay an initial fee and, by the first day of each anniversary of the Agreement, starting with the second anniversary, a minimum royalty of ten thousand dollars. JMHMD also received an equity grant equal to one-half of one percent of the then outstanding units of the Company on a fully-diluted basis. If we sublicense the technology, we are also required to pay an amount equal to 10% of the net sales of the sub-licensees.

Under the agreement, the Company is required to use commercially reasonable efforts to achieve the following milestones: (i) submit an investigational new drug application to FDA (or international equivalent) within one year of effective date of agreement, (ii) initiate a clinical trial utilizing bone marrow derived CD271+ Precursor Cells within three years of the effective date; provided, that any of the milestones may be extended for up to six months for a total of three times by notice and payment of a five thousand dollar extension fee. Failure to achieve these milestones within five years of the effective date triggers a right of termination by JMHMD. Otherwise, the agreement is to remain in effect until either the date all issued patents and filed patent applications have expired or been abandoned, or 20 years after the date of FDA approval of the last commercialized product or process arising from the patent rights whichever comes later. Further, each party has the right to terminate upon sixty days' prior written notice, or in the event of breach. If the Company sublicenses the technology, it is also required to pay an amount equal to 10% of the net sales of the sub-licensees. The Company to date has not incurred any royalty or sublicense related expense, but has paid $45,000 in license fees ($10,000 per year for 2021, 2020 and 2019) and for a $15,000 extension fee. In addition, the Company paid legal fees of approximately $25,000 for each of the years ended December 31, 2023 and 2022, in connection with the patent prosecution, issuance, and maintenance fees related to CD271+ technology.

In-licensed Patents and Applications

Bone Marrow Derived CD271+ Precursor Cells for Cardiac Repair. We have in-licensed the exclusive right to use CD271+ MSC precursors from bone marrow to treat certain aging-related conditions and diseases, such as frailty, Metabolic Syndrome, loss of muscle due to aging or frailty and neurocognitive disorders. That patent has issued in Australia, Brazil, Canada, China, Israel, Japan, South Korea, Mexico, New Zealand, Germany, Spain, France, the United Kingdom, Italy, Sweden, and Singapore. The patent application remains pending in the U.S While method of use claims may relate to the use of CD271+ cells for cardiac repair, our license terms exclude our use of CD271+ cells for preventing and treating cardiovascular diseases or disorders, including congenital cardiovascular defects. Assuming that all maintenance and annuity fees are paid, patents in this family are expected to expire in August 2031.

Trademarks

We have registered trademarks or applied for registered trademarks for "Longeveron" in the following jurisdictions. We have begun to phase out the registrations and applications for "LMSC" in favor of registrations for "LOMECEL-B™". In some jurisdictions multiple registrations and/or applications exist so that multiple goods and/or services may be listed:

Territory	"LOMECEL-B™"	"Longeveron"	"LMSC"
The Bahamas		Registered	Closed
Brazil		Registered	
Canada		Registered	
China		Registered	Registered
European Union		Registered	
Hong Kong		Registered	
India		Registered	
Japan		Registered	Registered
South Korea		Registered	
Morocco		Registered	Registered
Panama		Registered	
Switzerland		Registered	
Taiwan		Registered	
U.S.	Allowed	Allowed	Registered
Vietnam		Registered	

Government Regulation and Biologic Drug Approval

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. We believe that the FDA will regulate Lomecel-B™ as a biologic drug (i.e., a biologic) through the biologics license application ("BLA") process under the jurisdiction of the Center for Biologics Evaluation and Research ("CBER"). We intend to work with the FDA to confirm that a BLA is the most appropriate pathway and that CBER will be the FDA center responsible for review and licensure (i.e., approval). However, the FDA may disagree with us, in which case we will follow the FDA's recommendation. For future product candidates we will also confirm the appropriate approval pathway (i.e., BLA or new drug application ("NDA")) and the appropriate FDA center with regulatory oversight (i.e., CBER or the Center for Drug Evaluation and Research ("CDER")).

U.S. Biologic Drug Development Process

In the U.S., biologic drugs—or simply "biologics"—are regulated under two statutes: The Public Health Service Act ("PHS Act") and the federal Food, Drug, and Cosmetic Act ("FFDCA") and their implementing regulations. However, approval of only one application—typically either a BLA or an NDA—is required prior to marketing. Numerous FDA "Guidance Documents" and other materials address specific aspects of development for specific types of product candidates (e.g., cells, tissues, gene therapies, or vaccines). The process of obtaining approval and complying with applicable statutes and regulations requires substantial time and financial resources. Failure to comply with the applicable U.S. requirements before, during, or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold on ongoing clinical trials, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a biologic may be marketed in the U.S. generally involves the following steps:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations;
- submission of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site (or by one "commercial IRB") before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practice ("cGCP") requirements to establish the safety, purity, and potency (i.e., efficacy) of the proposed biologic for its intended use;
- submission of a BLA after completion of all clinical trials;
- satisfactory outcome of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of clinical investigation sites and the manufacturing facility or facilities at which the biologic is produced; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the U.S.

The specific preclinical studies and clinical testing that is required for a BLA varies widely depending upon the specific type of product candidate under development. Prior to beginning a human clinical trial with either a biologic or drug product candidate in the U.S., we must submit an IND that must become effective. The focus of an IND is the general investigational plan and protocol for the proposed clinical study. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls ("CMC") information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical hold is lifted and the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, including that all research subjects provide their informed consent to participate. Clinical trials are conducted under protocols detailing, among other things, the study objectives, safety monitoring, and effectiveness criteria. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Other submissions to an IND include protocol amendments, information amendments, IND safety reports and annual reports. Furthermore, an independent IRB for each clinical trial site (or a single "commercial IRB") must review and approve the protocol and informed consent form before the clinical trial may begin. The IRB also monitors the clinical trial until completed.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some clinical trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data monitoring committee ("DMC"). A DMC authorizes whether or not a study may move forward at designated check points based on access to certain data from the trial. The DMC may halt the clinical trial based on an unacceptable safety risk or on other grounds, such as a failure to demonstrate efficacy. Related reporting requirements for the sponsor, clinical investigator, and/or IRB also include IND safety reports and updating clinical trial results in public registries (e.g., ClinicalTrials.gov).

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects to test the safety, dosage tolerance, absorption, metabolism, distribution, excretion, side effects, and, if possible, early evidence of effectiveness. In the case of some products for severe or life-threatening diseases when the product may be too inherently toxic to ethically administer it to healthy volunteers, Phase 1 studies may instead be conducted in individuals who have the targeted disease or condition instead of healthy subjects.

- Phase 2: The product candidate is administered to a limited population of individuals who have the specified disease or condition to evaluate safety, preliminary efficacy, optimal dosages and dosing schedule, possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 (i.e., pivotal) clinical trials.

- Phase 3: Phase 3 clinical trials are generally the largest studies conducted at multiple clinical trial sites. The product candidate is administered to an expanded population that has the specified disease or condition to further evaluate dosage, provide statistically significant evidence of clinical efficacy and gain additional safety data. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Concurrent with clinical trials, sponsors usually complete additional animal studies, develop information about the chemical and physical characteristics of the biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must consistently produce quality batches of the product candidate. Furthermore, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final biologic. In addition, the sponsor must develop and test appropriate packaging, and conduct stability studies to demonstrate that it does not undergo unacceptable deterioration over its shelf life.

During the development of a new biologic, sponsors are given opportunities to meet with the FDA. These meetings typically occur prior to submission of an IND (i.e., pre-IND meeting), at the end of Phase 2 (i.e., EOP2 meeting), and before a BLA is submitted (i.e., pre-BLA meeting). Meetings at other times may be requested. These meetings provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use EOP2 meetings to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new biologic.

U.S. Review and Approval Process for Biologic Drugs

Assuming successful completion of all required testing, the sponsor submits a BLA containing the results of product development, preclinical and other non-clinical studies and clinical trials, descriptions of the manufacturing process, analytical testing, proposed labeling and other relevant information. The submission of a BLA is subject to the payment of a substantial application fee under the Prescription Drug User Fee Amendments ("PDUFA"). PDUFA fees apply to both drugs and biologics. Sponsors may seek a waiver of these fees in certain limited circumstances, including a waiver of the application fee for the first BLA or NDA submitted by a small business. Product candidates with an ODD are not subject to the BLA application fee unless the product application also includes a non-orphan indication.

The FDA reviews a BLA to determine, among other things, whether a biologic is safe, pure, and potent (i.e., effective) for its intended use and whether its manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Under PDUFA, the FDA has a goal date of ten months from the date a standard BLA is accepted for "filing" to review and act on the submission, and six months from the date of filing of a priority BLA. However, the time between submission and filing can add an additional two months as FDA conducts a preliminary review to ensure that the BLA is sufficiently complete to permit substantive review. Formal FDA review of the BLA does not begin until FDA has accepted it for filing. The FDA may refer an application in some cases to an advisory committee for its independent review. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation to FDA as to whether the application should be approved and under what conditions. The FDA is not bound by advisory committee recommendations, but it considers them carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the locations where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMPs and are adequate to assure consistent production of the product within required specifications. An important part of a BLA is a lot release protocol that the sponsor will use to test each lot of product made after BLA approval, as well as the FDA's own test plan that will be used for confirmatory testing of each post-approval product lot that is made before it is released to the public. If the FDA determines that the data and information in the application are not acceptable, then the FDA will outline the deficiencies and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA, it will either issue an approval letter or a Complete Response Letter ("CRL"). The approval letter authorizes commercial marketing of the biologic with approved prescribing information for specific approved indications. On the other hand, a CRL indicates that the review cycle of the application is complete, but the BLA cannot be approved in its present form. A CRL usually describes the specific deficiencies and the actions the sponsor must take to correct those deficiencies. A sponsor that receives a CRL must resubmit the BLA after addressing the deficiencies, withdraw the application, or request a hearing. Even if such additional data and information are submitted, the FDA may decide the resubmitted BLA still does not satisfy the approval criteria.

Following marketing approval, a sponsor may need to fulfill certain post-marketing requirements ("PMRs") or post-marketing commitments ("PMCs"). These may include Phase 4 studies that are used to gain additional experience from the treatment of patients for the intended therapeutic indication. The trials may be agreed upon prior to approval, or the FDA may require them if new safety issues emerge. A deferred pediatric study, if required (and not waived) under the Pediatric Research Equity Act ("PREA"), may also be conducted post-approval if the product includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration.

BLA approval may also include a risk evaluation and mitigation strategy ("REMS") that requires sponsor post-marketing regulatory efforts. A REMS is a safety strategy to manage a known or potential serious risk associated with a drug or biologic and to enable patients to have continued access to such medicines by managing their safe use. A REMS may include medication guides, physician communication plans, or elements to assure safe use ("ETASU") such as restricted distribution methods, patient registries, and other risk minimization tools.

FDA may withdraw the product approval if the sponsor does not comply with PMRs, PMCs, a REMS program, or other post-marketing requirements. The FDA may also request that a product be recalled for an identified safety issue. Finally, new legislative or regulatory requirements may be enacted or established, FDA policies may change, or FDA may not achieve its PDUFA goal dates, all of which could impact the timeline for development programs and regulatory approval.

FDA Expedited Review Programs for Serious Conditions

Under various statutory and regulatory authorities, the FDA has authority to review and approve certain products on an expedited basis if the products are intended to treat a serious condition and meet other requirements. These expedited programs are discussed below.

RMAT Designation. In 2017, the FDA established the regenerative medicine advanced therapy ("RMAT") designation as part of its implementation of the 21st Century Cures Act. Regenerative medicine therapies to treat, modify, reverse, or cure serious conditions and that meet the appropriate criteria may be eligible for RMAT designation as well as FDA's other expedited programs (i.e., fast track, breakthrough therapy, or priority review designations or accelerated approval). Regenerative medicine therapies receiving RMAT designation must meet the same standards for approval as any other biological product, including demonstrating the product's safety and effectiveness. As described in Section 3033 of the 21st Century Cures Act, an investigational product is eligible for RMAT designation if:

- It is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products (except for those regulated solely under Section 361 of the PHS Act and 21 C.F.R. Part 1271);
- It is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
- Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

A request for an RMAT designation can be included in a new IND, or submitted as an amendment to an existing IND. As with other expedited programs, the FDA can withdraw an RMAT designation that has been granted if the designation criteria are no longer met. Benefits of the designation include, among others, early FDA interactions, and accelerated approval based on surrogate or intermediate endpoints. Additionally, the RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies. Receiving an RMAT designation is not the same as receiving FDA product approval.

Fast-Track Designation. The fast-track designation is intended to expedite or facilitate the process for reviewing new drug and biologic drug products that meet certain criteria. Specifically, products are eligible for this designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The FDA may review sections of the marketing applications on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the application sections, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section. Receiving a fast-track designation is not the same as receiving FDA product approval.

Priority Review Designation. A product is eligible for priority review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. The FDA will attempt to direct additional resources to the evaluation of an application for a priority review-designated product in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to the standard ten months for review. Receiving a priority review designation is not the same as receiving FDA product approval.

Breakthrough Therapy Designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of a fast-track designation, as well as more intensive FDA interaction and guidance. If a product receives this designation, then the FDA will work to expedite the development and review of that product. Receiving a breakthrough therapy designation is not the same as receiving FDA product approval.

Accelerated Approval. A drug product intended to treat a serious condition may be eligible for accelerated approval upon a determination that the product provides a meaningful advantage over available therapies and has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require that a sponsor perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Accelerated approval is an approval pathway, not a designation like the other examples listed above.

Even if a product candidate qualifies for one or more of these programs, the standard for approval (i.e., safety and effectiveness) does not change. We may explore one or more of these opportunities for Longeveron product candidates as appropriate, as the programs are not mutually exclusive.

Marketing Exclusivity

In the case of biologic drugs, several types of marketing exclusivity may apply:

- Reference product exclusivity;
- Orphan drug exclusivity; and
- Pediatric exclusivity.

Reference Product Exclusivity

We believe that the FDA will regulate Lomecel-B™ as a new biologic and will require submission and approval of a BLA under the PHS Act. The PHS Act includes a framework for determining when a biologic is a "reference product" and therefore eligible for marketing exclusivity. The reference product is the single biological product against which a biosimilar (a product that is highly similar to and has no clinically meaningful differences from the reference product) or an interchangeable biosimilar (a product that is both biosimilar to, and will produce the same clinical result as, the reference product) is evaluated.

The FDA must determine the date of "first licensure" (i.e., approval) of a biologic which will, in turn, determine whether that biologic qualifies as a reference product that will be eligible for statutory exclusivity (and when such exclusivity will expire). Typically (but not always) the date of approval is the date of first licensure. The FDA will not approve a biosimilar or interchangeable biosimilar until the date that is 12 years after the date on which the reference product was first approved. However, the FDA may receive an application for a biosimilar or interchangeable biosimilar four years after the date on which the reference product was first approved. These 12- and four-year terms are each extended by six months if the product has been awarded pediatric exclusivity.

Legal uncertainties remain about the FDA's application of the date of first licensure and statutory exclusivity provisions to cell therapy products. At the appropriate time, we intend to provide information to the FDA so that the FDA can determine the date of first licensure of Lomecel-B™ (or any other product candidate that will be regulated as a biologic) and the date from which statutory exclusivity will begin to run. However, the FDA may not make an immediate decision about the date of first licensure at the time it approves a new biologic. Furthermore, there is currently no precedent showing how the FDA will apply this statutory framework to a cell therapy product. The law in this area will likely continue to evolve.

Orphan Drug Designation and Exclusivity.

Congress enacted the Orphan Drug Act in 1983 to spur development of drugs and biologics to treat diseases or conditions affecting few U.S. patients. The FDA may grant an ODD for a drug or biologic drug being developed to treat a "rare disease or condition," defined as affecting fewer than 200,000 persons in the U.S. or affecting more than 200,000 persons in the U.S. but for which there is no reasonable expectation that development costs will be recovered from U.S. sales of the product. A request for ODD must be submitted to the FDA before a marketing application is submitted (i.e., BLA or NDA), but there is no assurance that FDA will award an ODD if requested. In the fourth quarter of 2021, the FDA granted ODD to Longeveron's Lomecel-B™ for the treatment of HLHS.

An ODD does not change the regulatory review standards of safety and effectiveness and does not shorten the length of the FDA review or approval process. If an investigational product with an ODD subsequently receives the first FDA approval for the disease or condition for which it has such designation, then the approved product may be eligible to receive orphan drug exclusivity ("ODE") that prevents the FDA from approving any other applications to market the same drug or biologic for the same rare disease or indication for seven years, except in several specific circumstances including, among others, demonstrating clinical superiority of a new product vs. the product with ODE because of greater safety, greater effectiveness, or making a major contribution to patient care. Even if an investigational product has an ODD, there is no guarantee that the FDA will award ODE upon approval.

Competitors may receive approval of either a different product for the same use or indication, or the same product for a different use or indication. Approved drugs and biologics can also be used by physicians off-label, which is within the scope of their practice of medicine. Accordingly, ODE is not an absolute protection against potentially competing products. Moreover, an ODE awarded to another sponsor could block FDA approval of one of Longeveron's product candidates for seven years.

The law involving ODDs and ODEs, including the FDA's interpretation of "same drug," is continuing to evolve. Most notably, the U.S. Court of Appeals for the Eleventh Circuit issued a decision in *Catalyst Pharmaceuticals, Inc. v. Becerra* in September 2021 that significantly modified the FDA's longstanding interpretation and application of the scope of ODE. In *Becerra*, the court held that ODE applied to all uses or indications within an orphan-designated disease, not only to the approved use or indication within the designated disease as stated in FDA regulations and as applied by FDA in practice. Although FDA announced in January 2023 that it would only apply the *Becerra* court's decision to the specific parties involved in that case, it is possible that FDA could face additional administrative or legal challenges to its interpretation of the scope and applicability of ODD and ODE.

In addition to the potential award of a seven-year ODE upon product approval, the benefits of an ODD also include eligibility for certain research tax credits and a waiver of the marketing application fee otherwise required under PDUFA. An application for a prescription product with an ODD is not subject to an application fee unless the application also includes an indication for a non-rare disease or condition as well. Products with an ODD are also exempt from program fees otherwise required under the PDUFA. For fiscal year 2024, the application fee for a new drug or biologic requiring clinical studies is $4,048,695, and the program fee for approval of prescription drugs and biologics is $416,734.

Pediatric Exclusivity. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity (e.g., ODE) if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

Post-approval Requirements. Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. There also are continuing, annual program fees under PDUFA for any marketed products. Establishment registration of drug and biologic drug manufacturers and their subcontractors with FDA and certain state agencies subjects those entities to periodic unannounced inspections by the FDA for compliance with cGMPs, imposing certain procedural and documentation requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort for production and quality control to maintain compliance with cGMPs and other regulatory requirements.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;

- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of approved products. A company can make only those claims that were approved by the FDA in the application for marketing approval and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for certain patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of approved treatments, as the practice of medicine is outside the scope of FDA's authority. However, the FDA restricts manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal penalties against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

Other Healthcare Laws

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, the U.S. federal Anti-Kickback Statute, False Claims Act, Consumer Fraud Act, and other federal laws and regulations, as well as similar foreign laws in jurisdictions outside the U.S., where applicable, involving fraud and abuse, price reporting, data privacy and security, and transparency. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; requirements to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; requirements relating to pricing and marketing information; requirements to track and report gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities or that require the registration of pharmaceutical sales representatives; requirements regarding the registration of pharmaceutical sales representatives; and other applicable laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), thus complicating compliance efforts. Violation of any of such applicable laws or regulations may result in penalties, including, either separate or in combination and without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

Japanese Laws and Regulations

There are two primary Acts in Japan that regulate regenerative medicine development and offer two pathways to market for regenerative medicine therapeutic candidates: The Act pm the Safety of Regenerative Medicine ("ASRM") and the Pharmaceuticals and Medical Devices Act ("PMDA").

The ASRM allows physicians to provide cellular therapies to patients through an application process that is regulated by the Japanese Ministry of Health, Labor and Welfare ("MHLW"). Manufacturers of cell and gene therapy products wishing to utilize this pathway must identify and work with a partner clinic or hospital which enables the clinic to act as the distributor, with the manufacturer receiving a fee or a royalty, for example.

The PMDA includes special treatment for regenerative medicine products and identifies them as a stand-alone medical category with a novel "conditional approval" system. Sponsors seeking manufacturing approval need to provide clinical data to show that the product does not have any major safety concerns, clinical data to demonstrate "probable" efficacy, and satisfy established chemistry, manufacturing and controls criteria.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which the product will be covered and reimbursed by government payors (e.g., federal and state healthcare programs), third-party payors (e.g., commercial insurance and managed healthcare organizations), and other payors (e.g., foreign government healthcare programs). Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. For example, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by payors, that an adequate level of reimbursement will be established even if coverage is available or that the payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Decisions regarding the extent of coverage and amount of reimbursement to be provided are generally made on a plan-by-plan basis, meaning one third-party payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product, and require providers to show medical necessity for use, to each payor separately. This process can be time-consuming, with no assurance that coverage and adequate reimbursement will be applied consistently or even obtained.

Similar challenges to obtaining coverage and reimbursement for pharmaceutical or biological products will apply to companion diagnostics. For example, for products administered under the supervision of a physician, the difficulty in obtaining coverage and adequate reimbursement may be increased because of the higher prices often associated with such drugs. Additionally, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement of the companion pharmaceutical or biological product. However, separate reimbursement for the product itself, the companion product, or the treatment or procedure for which the product is used may not be available, which, in turn, may also impact utilization.

Payors are also increasingly reducing reimbursements for pharmaceutical products and services through continued implementation of cost-containment programs, including price controls and value-based care initiatives, requirements for substitution of generic products and restrictions on coverage and reimbursement, which could further limit sales of any product. In addition, payors continue to question safety and efficacy while also challenging the prices charged, examining medical necessity, and reviewing the cost effectiveness of pharmaceutical products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases of this nature surrounding reimbursement for any product or a decision by a government and third-party payor not to cover a product could result in reduced physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability of manufacturers to sell products profitably.

Healthcare Reform

In the U.S. and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("ACA") was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the U.S. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the Average Manufacturer Price ("AMP") or the difference between AMP and "best price," whichever is greater; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected (often referred to as "5i drugs"); expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges that would either repeal, or repeal and replace, all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated, effective January 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 Consolidated Appropriations Act permanently eliminated, effective January 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 2021, also eliminated the health insurer tax. Other legislative changes have also been adopted since the ACA was enacted, including mandatory sequestration (e.g., aggregate reductions of certain Medicare payments of up to 2%), which will remain in effect through fiscal year 2031 absent Congressional action.

We expect such judicial and Congressional challenges to continue. There has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to reform government program reimbursement methodologies for pharmaceutical products and bring more transparency to product pricing and the relationship between pricing and manufacturer patient programs.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, which amends the FFDCA, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

On July 9, 2021, President Biden signed the "Executive Order on Promoting Competition in the American Economy," which is focused on increasing competition in several industries, including the pharmaceutical and biotechnology industries. Among other things, the Executive Order directs the Department of Health and Human Services to increase support for generic and biosimilar drugs, continue to improve the approval framework for generics and biosimilars, to issue a comprehensive plan to combat high prescription drug prices and price gouging, identify efforts to impeded generic and biosimilar competition, and to standardize plan options in the National Health Insurance Marketplace to improve competition and consumer choice. The Executive Order also encourages the FTC to ban unfair anticompetitive conduct or agreements such as "pay for delay" and similar agreements, in which brand-name drug manufacturers pay generic drug manufacturers to stay out of the market, resulting in an estimated $3.5 billion increase in drug prices per year.

Human Capital Management

As of December 31, 2023, we had 23 full-time employees, one part-time employee and one full-time consultant. Among those, four had M.D. or Ph.D. degrees, two are Certified Public Accountants, and one has a J.D. degree. Of these full-time employees and consultants, 18 are engaged in research and development activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

See Part III of the Original Form 10-K for information about our Executive Officers, non-employee Directors and other key employees.

Available Information

The Company was formed as a Delaware limited liability company in October 2014 and converted into a Delaware corporation in February 2021 in connection with our initial public offering ("IPO"). Our principal executive offices are located at 1951 NW 7th Avenue, Suite 520 Miami, Florida 33136 and our telephone number is (305) 909-0840.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are filed with the Securities and Exchange Commission ("SEC"). We are subject to the informational requirements of the Exchange Act, and we file or furnish reports, proxy statements and other information with the SEC. Such reports and other information we file with the SEC are available free of charge at our website www.longeveron.com when such reports are available on the SEC's website. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. Longeveron periodically provides other information for investors on our corporate website, including press releases and other information about financial performance, information on corporate governance and presentations. Our website address is www.longeveron.com, and we make our filings with the SEC available on the Investor Relations page of our website. Our references to website URLs are intended to be inactive textual references only. The information found on, or that can be accessed from or that is hyperlinked to, our website does not constitute part of, and is not incorporated into, this Amendment. Our Class A common stock is traded on the Nasdaq under the symbol "LGVN".

Part IV

Item 15. Exhibits and Financial Statements Schedules

a. (1) Financial Statements:

Not applicable.

(2) Financial Statement Schedules

Not applicable.

Exhibit Number	Description of Exhibit
31.1	Certification of the Chief Executive Officer pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
31.2	Certification of the Chief Financial Officer pursuant SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished herewith
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, furnished herewith
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LONGEVERON INC

March 11, 2024

By: **/s/** Mohamed Wa'el Ahmed Hashad
Mohamed Wa'el Ahmed Hashad
Chief Executive Officer

SIGNATURES

In accordance with the Exchange Act, this Amendment No. 1 to the Annual Report of Longeveron Inc. on Form 10-K/A has been signed below by the following persons on behalf of the registrant and in the capacities indicated and, on the dates, indicated.

Signature	Title	Date
/s/ Mohamed Wa'el Ahmed Hashad Mohamed Wa'el Ahmed Hashad	Chief Executive Officer (principal executive officer)	March 11, 2024
/s/ Lisa A. Locklear Lisa A. Locklear	Executive Vice President and Chief Financial Officer (principal financial officer and principal accounting officer)	March 11, 2024

Exhibit 31.1

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Wa'el Hashad, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report of Longeveron Inc. on Form 10-K/A;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2024

/s/ Wa'el Hashad
Wa'el Hashad
Chief Executive Officer

Exhibit 31.2

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Lisa A. Locklear, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report of Longeveron Inc. on Form 10-K/A;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2024

/s/ Lisa A. Locklear

Lisa A. Locklear
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with Amendment No. 1 to the Annual Report of Longeveron Inc. (the "Company") on Form 10-K/A for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wa'el Hashad, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2024

/s/ Wa'el Hashad
Wa'el Hashad
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with Amendment No. 1 to the Annual Report of Longeveron Inc. (the "Company") on Form 10-K/A for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lisa A. Locklear, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec. 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2024

/s/ Lisa A. Locklear
Lisa A. Locklear
Executive Vice President and Chief Financial Officer